September 23, 2002

James A. Deyo, D.V.M., Ph.D., D.A.B.T.
Technical Associate
Eastman Chemical Company
P. O. Box 431
Kingsport, Tennessee 37662

Dear Dr. Deyo:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for ethylene glycol diacetate, posted on the ChemRTK HPV Challenge Program Web site on May 31, 2002. I commend Eastman Chemical Company for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its HPV Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the attached comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that Eastman Chemical Company advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the HPV Challenge Program Web site "Submit Technical Questions" button or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

/s/

Oscar Hernandez, Director
Risk Assessment Division

Attachment

cc: C. Auer
A. Abramson
M. E. Weber

EPA Comments on Chemical RTK HPV Challenge Submission:
Ethylene Glycol Diacetate (EGD)

SUMMARY OF EPA COMMENTS

The sponsor, Eastman Chemical Company, submitted a test plan and robust summaries to EPA for ethylene glycol diacetate (CAS No. 111-55-7; EGD) dated May 1, 2002. EPA posted the submission on the ChemRTK HPV Challenge Web site on May 31, 2002.

EPA has reviewed this submission and has reached the following conclusions:

1. Physicochemical Properties and Environmental Fate. Except for biodegradation and fugacity, all appropriate SIDS-level tests/estimations have been performed. The fugacity model should have used the available measured data. The submitter needs to revise the biodegradation robust summary with data from the original study so that data adequacy can be determined.

2. Health Effects. Adequate data are available for the acute and genetic toxicity endpoints. EPA agrees that data from a surrogate, ethylene glycol, can be used for the repeated-dose and reproductive/developmental endpoints. However, these data were not available for review. Therefore, EPA reserves judgment on this aspect of the test plan.

3. Ecological Effects. The submitted ecotoxicity data are adequate and no further testing is required.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

EPA COMMENTS ON THE ETHYLENE GLYCOL DIACETATE (EGD) CHALLENGE SUBMISSION

Test Plan

Chemistry (melting point, boiling point, vapor pressure, partition coefficient, and water solubility).

Adequate data are available for all endpoints for the purposes of the HPV Challenge Program.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity).

Adequate data are available for photodegradation and stability in water.

Fugacity. The submitter used estimated input properties rather than available measured properties. The use of measured input values is strongly recommended.

Biodegradation. The submitted robust summary is based on a secondary source and has few details. The robust summary needs to incorporate details from the original study so that data adequacy can be determined.

Health Effects (acute toxicity, repeat dose toxicity, genetic toxicity, and reproductive/developmental toxicity)

Adequate data are available for the acute and genetic toxicity endpoints. The submitter proposes to use data on ethylene glycol (EG) to support the existing EGD data for the repeated-dose toxicity endpoint and to address the reproductive/developmental toxicity endpoints. The submitter believes that EG is an acceptable surrogate for EGD based on the well-known conversion of alcohol/glycol esters to the parent alcohol/glycol, which is responsible for the systemic toxicity. While EPA agrees that EG is most likely an acceptable surrogate for EGD, the robust summaries for EG are not available (the submitter states that they will be available under the International Council of Chemical Associations (ICCA) High Production Volume Initiative). Consequently, EPA defers judgment on whether the repeated-dose and reproductive/developmental toxicity endpoints are adequately addressed until the EG robust summaries are available for review.

Acute Toxicity. Although the existing study is old and lacks important details, the reported LD50 is supported by the results from the two repeated-dose toxicity studies. No additional testing is necessary.

Ecotoxicity (fish, invertebrates, and algae).

Adequate data are available for these endpoints for the purposes of the HPV Challenge Program.

Specific Comments on the Robust Summaries

Health Effects.

Acute Toxicity. Information missing from the robust summary includes the purity of the test material, administered dose in mg/kg, period of post-treatment observation, and method of LD_{50} calculation.

Repeated-Dose Toxicity. Study details missing from the robust summaries are the purity of the test material, method details, numbers of animals per dose level, frequency of data collection, statistical methods, specific hematology and clinical chemistry endpoints, and specific organs that were weighed and examined histopathologically.

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.